

PATENT COOPERATION TREATY

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From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT
10/541685

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/000554

International filing date (day/month/year)
10.01.2004

Priority date (day/month/year)
10.01.2003

International Patent Classification (IPC) or both national classification and IPC
A01N25/02, A01N57/20, A61K9/107

Applicant
BATTELLE MEMORIAL INSTITUTE

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Romano-Götsch, R

Telephone No. +49 89 2399-8874



**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2004/000554

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
☐ a sequence listing
☐ table(s) related to the sequence listing
 - b. format of material:
☐ in written format
☐ in computer readable form
 - c. time of filing/furnishing:
☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

- ☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).
- ☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:

- ☐ paid additional fees.
- ☐ paid additional fees under protest.
- ☐ not paid additional fees.

2. ☒ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

- ☐ complied with
- ☒ not complied with for the following reasons:

see separate sheet

4. Consequently, this report has been established in respect of the following parts of the international application:

- ☒ all parts.
- ☐ the parts relating to claims Nos.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3,12-16,18-20,22-27,36,37,39,40,42-50
	No: Claims	1,2,4-11,17,21,28-35,38,41
Inventive step (IS)	Yes: Claims	22-26,39,40,42-50
	No: Claims	1-21,27-38,41
Industrial applicability (IA)	Yes: Claims	1-50
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item IV

Unity of Invention

The Applicant's attention is directed to the fact that the present application does not meet the requirements of unity of invention according to Rules 13(1) and (2) PCT.

Examining the possible correspondence by technical effect, one finds that the technical effect of the first invention (claims 1-20, 27-29, 31-37) is an improved carrier system for the release in-vivo of polar drugs over D1.

The technical effect of the second invention (claims 1-20, 27-29, 31-37 (all in part) and claims 21-26, 30, 38-50) is a sprayable herbicide composition with improved efficiency over D3.

This appears to show lack of corresponding technical effect. Consequently, the objective problem underlying the subjects of the claimed inventions does not allow for a relationship to be established between the said inventions, which involves a single general inventive concept.

This Authority has selected not to invite the Applicant to pay additional fees. However, the Applicant is advised, that an objection of lack of unity of invention will be raised upon entry in European regional phase.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents, cited in the International Search Report or in the application:

D1: WO-A-92 08445

D2: Costa, S.M.B. et al., Journal of Photochemistry and Photobiology A: Chemistry, 142, (2001), 151-161

D3: GB-A-2 022 418

Novelty

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-37 is not new in the sense of Article 33(2) PCT.

D1 discloses (p.2, line 4,-p.3, line 17) non aqueous oil-continuous microemulsions containing a polar drug dissolved in a non-aqueous internal phase polar solvent (e.g. polyhydric alcohol, polyethylene glycol), dispersed with an emulsifier such as lecithin (preferably in liquid form, i.e. dissolved in soybean oil, see p.3, line 7) in an alkyl fatty acid ester. Thus, D1 anticipates the novelty of claims 1,2,4,6-11,17,28,29,31-35.

D2 discloses (p.152, left column, and p. 158, right column, par.3.5.2) non aqueous oil-continuous microemulsions containing the polar compound Methyl Viologen (1,1'-dimethyl-4,4'-bipyridinium dichloride) dissolved in ethylene glycol, dispersed with sodium 1,4-bis-2-ethylhexyl sulfosuccinate (AOT) in n-heptane. Since 1,1'-dimethyl-4,4'-bipyridinium dichloride is also a bipyridyl herbicide, D2 anticipates the novelty of claims 1,5,8,9-11,17,21, 28, 30, 38, 41.

The subject-matter of claims 3,12-16, 18-20, 22-27,36,37,39, 40, 42-50 is not disclosed in D1 or D2 and thus meets the requirements of art. 33(2) PCT.

D3 and D4 do not affect the novelty of presently claimed matter.

D3 discloses **aqueous** water-in oil emulsions of mean particle size below 10 microns, wherein at least one water soluble herbicide (p.2, lines 25-42) dissolved in water is mixed with an oil phase dispersed with an emulsifier. D3 does not disclose non-aqueous microemulsions.

Inventive Step

The present application does not meet the criteria of Art. 33(1) PCT, because the subject-matter of claims 1-21, 27-38, 41 does not involve an inventive step in the sense of Art. 33(3) PCT, as explained below.

In view of the novelty objections above, an inventive step for claims 1,2,4,6-11,17,21, 28,29-35,38, 41 cannot be acknowledged.

D3 is regarded as the closest prior art and discloses electrostatically sprayable ready-for-use formulations comprising aqueous water-in oil emulsions of mean particle size below 10 microns, wherein at least one water soluble herbicide.

According to the application, the presence of water in such sprayable formulations results in a reduced penetration in plants' leaves, because the herbicide dissolved in water goes partially lost, due, e.g. to the generation of droplets of various sizes and consequent bouncing off or drifting away, water evaporation with subsequent solidification of the herbicide on the leaves, etc.

The subject-matter presently on file differs from D3 in that water has been replaced with a polar solvent, thus obtaining non aqueous oil-continuous microemulsions.

Departing from D3, the problem to be solved by the present invention may be regarded as the provision of sprayable herbicide water-in-oil microemulsions with improved penetration efficiency.

The solution proposed in claims 1-20, 27-29, 31-37 of the present application consists in the provision of a non aqueous oil-continuous microemulsions having a polar compound component dissolved in the polar solvent in the inner core of the microemulsions. However, there is no requirement in said claims, according to which the polar compound has to be a polar agrochemical complex. This feature is indispensable for the function of the invention in the light of the technical problem which it seeks to solve.

In view of the fact that this essential feature is missing in independent claims 1 and 28, and dependent claims 2-20, 27, 29, 31-37, the solution proposed in said claims does not solve the technical problem (Art.33(3) PCT).

Dependent claims 22-26, 39, 40, 42 and independent claims 43-46, 48-50, which are novel and which require the presence of an agrochemical complex, are regarded as inventive because replacing water with a non-aqueous polar solvent in the oil-continuous microemulsions is not suggested in D3.

D1 and D2 are directed to different technical problems: D1 teaches an improved drug release system for polar drugs; D2 aims at the determination of solute partition and the changes of viscosity/polarity in non-aqueous, oil-continuous microemulsions. Thus, the skilled person would not have considered the teaching of D1 or D2 to improve the penetration on plants'leaves of herbicide sprayable formulations of D3.